Docket No. KM-FLEX-1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Mansmann)
Serial No. ~~10/011,933~~ 10/071,930) Examiner: C.M. Gilpin
) Group Art Unit: 3738
Filed November 30, 2001)

Title: CARTILAGE REPAIR IMPLANT WITH SOFT BEARING SURFACE AND FLEXIBLE ANCHORING DEVICE

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS NON-FEE AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on January 12, 2004.

Name of Registered Representative: Patrick D. Kelly

Signature: Patrick D Kelly

Date: 12 Jan 2004

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FIRST RESPONSE WITH AMENDMENTS

MS NON-FEE AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This response with amendments is submitted in response to an office action mailed on July 10, 2003. A Petition for a 3-month extension of time is also enclosed.

An Information Disclosure Statement (including a Form PTO/SB/08) is also enclosed, along with the proper fee for late submission, and copies of the cited prior art.

Attachment A contains amendments to the claims. The remarks below relate to those amendments, and describe a number of respects in which the invention (as now claimed) differs from the prior art.

The Examiner's comments and analysis in the Office Action

are sincerely appreciated, since they clearly pointed out that the claims as originally submitted failed to adequately define the invention, or distinguish it from the prior art. Accordingly, the claims have been completely redrafted. The Examiner is requested to completely cancel all original claims, which were claims 1-12, and substitute therefor newly drafted claims 13-31.

The clearest way to distinguish this invention, as now claimed, over the prior art is to analyze it in comparison to each of the key items of prior art, in turn.

Comparison to Oka et al, US 5,314,478

Claims 1,2, 10, and 11 were rejected for lack of novelty, based on Oka et al, US patent 5,314,478.

Oka's '478 patent gave a cursory nod in the direction of replacing hyaline cartilage in a joint, then the entire remainder of that disclosure was focused entirely on repairing intervertebral disks, in spines. This becomes evident by comparing Figure 1, which is the only figure that relates to hyaline cartilage in joints (and which did not even have proper callout numbers), to the other nine figures (including the graph), all of which relate to intervertebral disks in spines, rather than to hyaline cartilage in disks.

The cartilage in intervertebral disks is a completely different type of cartilage, called "*fibro*-cartilage", which has a totally different structure and performance, compared to hyaline cartilage, in a flexible joint. Each fibro-cartilage disk in the spine is heavily interlaced, throughout its entire structure and thickness, by thousands of tiny fibers that also extend into the hard bone surfaces of the two vertebral bones that flank that disk. That fibrous structure is specifically designed to never allow any sliding or shear motion, at all, between adjacent vertebral bones in the spine. If sliding and shear motion were allowed between adjacent vertebral bones, it would pinch, damage, and even destroy the spinal cord. By contrast, hyaline cartilage (i.e., the smooth-surfaced and slippery cartilage that coats bone surfaces in joints such as

knees, hips, etc.) is totally different, and evolved specifically to allow and promote sliding and shear motion, between adjacent bones.

This explains why each and all of the drawings in Figures 2 through 5(b), in Oka et al '478, show sandwich-type structures, having layers of hard material on both the top and the bottom layers, flanking a middle layer of a soft shock-absorbing gel material, made of polyvinyl alcohol (PVA).

The chemistry of Oka's PVA material, and its potential for use in sandwich structures for spinal disc repair, was the focus of Oka and his coworkers, and it helps explain why their drawing in FIG. 1 had no practical and useful information, for anyone who is already skilled in surgical implants and who is trying to overcome the very real barriers that have frustrated and thwarted the development of actual, useful, functional and durable plugs, for insertion into actual joints in patients with damaged cartilage.

The only thing shown in FIG. 1 of the Oka et al '478 patent is a purported cross-section of one end of a femur bone, with a segment of bone and a segment of cartilage purportedly replaced by a synthetic plug, having a hard material at the bottom (such as a porous ceramic, shown by callout letter C1), and a layer of gel material on top (shown by callout letter g). That drawing and teaching, even when considered in light of every additional teaching in the specification, would be quickly dismissed as unworkable and impractical, by any expert who is working in this field of surgery or research. In particular, it completely fails to offer any teachings, guidance, or even suggestive hints as to how two crucially important problems can be overcome.

The first problem centers on how the implant can be prevented from being moved, jostled, or rotated, after it has been implanted into a joint such as a knee, during a healing and recovery period that will require weeks or months until sufficient bone tissue grows into the anchoring portion of the implant to provide a secure anchoring. Rather than helping to repair and heal a cartilage defect, the implant as taught would

turn instead into a grinding device, which would soon begin damaging the bone surrounding the implant.

The second unanswerable question is how the hydrogel layer, on top of the implant shown in Oka's Figure 1, can be installed in a way that provides a smooth seam, or boundary, between the implanted hydrogel surface, and the surrounding native cartilage surface. As any skilled surgeon or implant researcher would immediately recognzie, that implant as drawn and taught will have small but abrasive edges, between the implant hydrogel, and the surrounding cartilage surfaces. Those small edges will quickly begin to abrade and eventually destroy the opposing hyaline cartilage surface, which will be rubbing against the ridges and seams between the implant hydrogel, and the native cartilage.

Even though an examiner allowed their claims, Oka and his coworkers had no way to develop their claimed invention into practical and useful implants with smooth surfaces, for articulating joints. The only potentially significant value of their disclosures was limited to (i) polyvinyl alcohol chemistry; and, (ii) repair of intervertebral discs in the spine, using sandwich-type implants with a center layer of soft hydrogel, placed between two outer layers of hard ceramic or titanium mesh.

By contrast, the implant disclosed herein can successfully answer both of the questions mentioned above. Problems relating to rapid-yet-secure anchoring, which must be strong enough to endure during a recovery and healing process before bony tissue has had time to grown into the anchoring layer, can be overcome successfully by means such as anchoring pins and cement. However, it is recognized that no one single anchoring pin (or any other single anchoring protrusion, acting by itself) can provide the strength that will be necessary to securely withstand all of the compressive, shear, rotating, and other forces and stresses that will occur inside a knee or other joint. Therefore, the claims, as amended, now refer to a "plurality" of anchoring protrusions.

It also should be noted that the term "protrusion" is used by the Applicant in its conventional sense, to refer to a component that protrudes beyond some type of "baseline" plane,

surface, or location. By contrast, it is not clear at all whether the bottom surface of a single monolithic implant (as illustrated in Oka's Figure 1) might be labelled or deemed a "protrusion", all by itself, since the entire implant arguably protrudes down into the surface of the femur bone.

However, any theoretical need to answer that question has been sidestepped, cleanly and clearly, by simply referring in the claims below to "a plurality of anchoring protrusions". That type of structure is not shown or suggested in any way by Oka et al '478.

With regard to the fact that the Oka et al '478 patent left crucial questions unanswered, the reality is that Oka and his coworkers, instead of trying to design actual implants for articulating joints, were trying to stake out a position in one particular type of polymer (i.e., polyvinyl alcohol), which looked promising in the early 1990's. Oka and his coworkers were hoping that other skilled researchers, who were actually trying to design improved orthopedic implants and who could go beyond the simplistic drawing used as Fig. 1 in Oka et al, would begin using PVA polymers, in whatever types of implants those other experts came up with. That much becomes clear, from an informed reading of their patent, and of other articles published at around that time by Oka and his coworkers.

However, as it turns out, the PVA polymer has now been passed up and rendered obsolete, in research on cartilage repair implants. Other synthetic polymers are substantially stronger and more durable, and can be surface-treated by chemicals that render them extraordinarily slippery when coated with synovial fluid, the liquid that provides lubrication in mammalian joints. The Applicant herein is at the forefront of research on hydrogels made from surface-treated synthetic polymers, and has recently filed a separate and additional patent application on a major recent discovery in that field of research.

Finally, it should also be noted that various additional items of cited art are enclosed herewith, along with an Information Disclosure Statement, to provide additional art on

other efforts to develop implants for replacing cartilage. However, as can be seen by a review of those patents, the invention, as now claimed, is substantially different from each and all of those devices.

Comparison to Wall, US 4,502,161

Claims 3-6 and 7-9 were also rejected for obviousness, under 35 USC 103, in view of Oka et al '478 combined with Wall '161.

While the comments above regarding Oka should be sufficient to overcome that rejection, it should also be noted that Wall '161 apparently relates solely to replacing meniscal segments, rather than cartilage segments that are affixed to articulating bone surfaces. Meniscal segments (exemplified by the two meniscal segments in each knee) are wedge-shaped segments, which are slippery on both of the two main sides of the wedge. Each wedge is positioned between a femoral runner and a tibial plateau, in a way that allows it to move between both of the bones positioned above and below it.

Accordingly, with only very minor exceptions near the tips of the wedges, meniscal wedges are not affixed to bone, at all. Instead, their peripheral (outer) surfaces are connected to the soft tissue (tendons and ligaments) that form the capsule which surrounds the knee joint and holds in the synovial fluid, while their ends at attached to fibrous strands, which circle around the femoral runners and attach to protrusions in the middle of the tibial plateau.

For that reason, none of the attachment components disclosed in Wall '161 are designed or intended as protrusions. None of them will be inserted into bone. Instead, all of those attachment devices are designed as flaps, which will be screwed to a bone surface that is accessible, adjacent to the joint.

In fact, that design was highly impractical, and was never commercialized. If the type of meniscal wedge suggested by Wall were made of stiff material, it would not be able to emulate the flexible and adaptable meniscal segments that are naturally positioned inside a knee (or similar labrum segments, in a

shoulder), and it would quickly begin to abrade and cut into the cartilage surfaces it is intended to help support. Alternately, if made of a flexible material, any such meniscal flap would simply be squeezed (rather quickly) out of its position between two bones under compression.

If the examiner wishes to know more about meniscal segments, the types of reinforced hydrogels that will need to be provided for them, and the anchoring requirements that will need to be satisfied, she is invited to read US patent 6,629,997, by the same inventor herein, which specifically addresses meniscal segments. However, it should be recognized from the outset that meniscal segments are substantially quite different from hyaline cartilage that covers the rounded end of a bone.

De La Torre, US 5,368,602

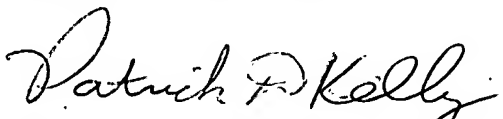
The flexible surgical meshes patented by de la Torre are also substantially different from the flexible anchoring devices disclosed in the subject invention, and there is absolutely no suggestion, anywhere in de la Torre, which implies in any way that those flexible meshes should be used as bone anchoring segments. Even if bony tissue were to grow entirely through and around a single layer of flexible mesh, it could not provide the type of anchoring strength that is required for a cartilage implant.

Instead, to provide adequate anchoring strength for a cartilage implant, the anchoring portion must have substantial thickness. This is implied by the fact that the bone ingrowth pad 130, as shown in FIG. 1 and as referred to throughout the application as a "pad" (rather than a sheet), can promote "ingrowth by bony tissue". The reference to "ingrowth" clearly implies that bony tissue will indeed grow ***in*** to the pad; by contrast, if that layer was merely a thin sheet without any substantial thickness, bony tissue would merely grow through it, and quickly come out the other side, with little or no reinforcing strength.

CONCLUSION

In view of the foregoing amendments and remarks, it is believed that the claims, as amended, are now in condition for allowance. If any questions remain, please contact the undersigned attorney at 314-822-8558.

Respectfully submitted,



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